

EPA REGISTRATION NUMBER 81598-12

Material Sent for Data Extraction

Reg # 81598-12

Description: PBN

Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☒ Notification Dated 11/20/13

☐ New CSF(s) Dated _____

☐ Other: _____

Decision #: 485106

Other Action/Comments: _____

Do not file this cover sheet. Please discard after processing.

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Mindy Ondish

Phone: (703)605-0723 Division: RD/PM Team 25

Date: 11/26/13



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

November 20, 2013

Cheryl Wagner, Agent
Rotam Limited
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707

Subject: Notification per PR Notice 98-10 (change primary brand name)
Rotam Dicamba Technical
EPA Reg. No. 81598-12
Application Dated November 11, 2013

Dear Ms. Wagner:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the subject product. The Registration Division (RD) has conducted a review of this request and finds that the action falls within the scope of PRN 98-10. The primary brand name for this product has been changed from "Ritter Dicamba Technical" to "Rotam Dicamba Technical". This notification acknowledgement will be uploaded onto PPLS without a label.

If you have any questions, please contact Mindy Ondish at (703)605-0723 or at ondish.mindy@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Mindy Ondish, for".

Kathryn V. Montague
Product Manager 23
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs



Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

November 11, 2013

Document Processing Desk (NOTIF)
ATTN: Kathryn Montague, PM Team 23
Registration Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Dear Ms. Montague,


**Subject: Ritter Dicamba Technical, EPA Registration Number 81598-12
Notification of Change in Primary Brand Name**

Wagner Regulatory Associates, Inc., as agent for Rotam Limited, respectfully notifies the Agency of a change in the primary brand name Ritter Dicamba Technical to **Rotam Dicamba Technical**. In support of this notification, the following documents are enclosed:

- Letter from Rotam Limited appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Notification (8570-1)
- 1 copy of the label

If you have any questions about this submission please contact the undersigned at Cheryl@wagnerreg.com or (302) 635-7289.

Respectfully submitted,


Cheryl Wagner
Agent for Rotam Limited

Enclosures



United States
Environmental Protection Agency
 Washington, DC 20460

<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 81598-12	2. EPA Product Manager Kathryn Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Rotam Limited/Ritter Dicamba Technical	PM# 23	
5. Name and Address of Applicant (Include Zip Code) Ritter Chemical, LLC c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name: _____	

NOTIFICATION**NOV 20 2013****Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Notification of change in primary brand name to Rotam Dicamba Technical. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
	If "Yes" No. per Unit Packaging wgt. container	If "Yes" No. per Package wgt. container		<input type="checkbox"/> Plastic	
* Certification must be submitted				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) HDPE lined bags	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.5 gallons		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Cheryl Wagner		Title Agent for Rotam Limited		Telephone No. (Include Area Code) (302) 635 7289	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received <div style="text-align: center;">(Stamped)</div>
2. Signature 		3. Title Agent for Rotam Limited			
4. Typed Name Cheryl Wagner		5. Date November 11, 2013			

U.S. Environmental Protection Agency
Office of Pesticide Programs (7505P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

February 15, 2012

Re: Designation of Agent

Dear Sir or Madam:

This letter serves as notification that ROTAM LIMITED (Firm Number: 81598) has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as its Agent regarding all pesticide registration matters the company may have with the U.S. Environmental Protection Agency (EPA).

ROTAM LIMITED hereby authorizes EPA to contact any of the following individuals within WRA, Inc. on behalf of the company:

James M. Wagner
Managing Director
Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707
Telephone: (302) 635-7290
Fax: (302) 635-7295
Email: james@wagnerreg.com

Cheryl R. Wagner
President
Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707
Telephone: (302) 635-7289
Fax: (302) 635-7295
Email: Cheryl@wagnerreg.com

Catherine M. Bryd
Regulatory Associate
Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707
Telephone: (302) 635-7283
Fax: (302) 635-7295
Email: Catherine@wagnerreg.com

Lori Kohler
Regulatory Associate
Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707
Telephone: (302) 635-7281
Fax: (302) 635-7295
Email: Lori@wagnerreg.com

Barbarette Young-Henry
Regulatory Associate
Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707
Telephone: (302) 635-7279
Fax: (302) 635-7295
Email: Barbarette@wagnerreg.com

Authorization to contact these staff members within WRA, Inc remains in effect until such time that ROTAM LIMITED provides notification in writing of any changes.

Respectfully submitted,

For and on behalf of
ROTAM LIMITED

.....
Authorized Signature

Yifan Wu
Vice General Manager
Tel: 86-512-5790 3076
Email: yifanwu@rotam.com

cc: WRA, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 18, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

MS. CHERYL WAGNER
WAGNER REGULATORY ASSOCIATES, INC., AGENT FOR
ROTAM LIMITED
P.O. Box 649
HOCKESSIN, DE 19707-

Dear Ms. Wagner:

Subject: Transfer of Pesticide Registrations and Data From Company Number 9468 to Company Number 81598

Pursuant to your request in your letter and transfer agreement of August 14, 2013, we have approved the transfer of the following registrations from **ITTER CHEMICAL, LLC**, company number **9468** to **ROTAM LIMITED**, company number **81598**.

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Reg. No.	New EPA Reg. No.
ITTER DICAMBA TECHNICAL	9468-45	81598-12

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to distribution or sale of the product containing the new registration number. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

With regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The annual maintenance fee is based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated August 14, 2013 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date **ROTAM LIMITED** will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Louis Vaughn at (703) 308-8114.

Sincerely,



Steve Robbins, Chief
Information Services Branch
Information Technology & Resource Management Div. (7504P)

cc: MS. JANELLE KAY
PYXIS REGULATORY CONSULTING, INC., AGENT FOR
RITTER CHEMICAL, LLC
4110 136TH STREET, N.W.,
GIG HARBOR, WA 98332-

RE: L_9468_RAD_81598_09_18_2013

APPENDIX A

MRID or other Identifying Administrative Number	Name of the Study	Name of Person or Lab that Conducted the Study	Date the Study was Submitted to EPA
48420501	Tillman, A. (2011) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Ritter Dicamba Technical. Project Number: RC/201006. Unpublished study prepared by Ritter Chemicals, LLC.	Ritter Chemical, LLC	3/16/2011
48420502	Li, H. (2011) Preliminary Analysis and Enforcement Analytical Method of Dicamba TGAI - Validation of Analytical Methodology for the Assay of Active Ingredient and Related Significant Impurities and Subsequent 5-Batch Analysis of Dicamba TGAI. Project Number: NC/2007/024. Unpublished study prepared by Nutrichem Laboratory Co., Ltd. 91 p.	Nutrichem Laboratory Co., Ltd.	3/16/2011
48420503	Weller, P. (2011) Group B - Product Chemistry Analysis of Dicamba Technical. Project Number: 381100/1/001. Unpublished study prepared by MRIGlobal. 37 p.	MRIGlobal	3/16/2011
48420504	Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	Ritter Chemical, LLC.	3/16/2011

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

December 13, 2011

COURIER DELIVERY

Kathryn Montague (PM 23)
Document Processing Desk (**FNL LBL**)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

RE: Ritter Chemical, LLC
Ritter Dicamba Technical (EPA Reg. No. 9468-45)
Submission of Final Product Labeling per the Agency Letter dated October 3, 2011

Dear Ms. Montague,

On behalf of Ritter Chemical, LLC, please find the enclosed final product labeling for Ritter Dicamba Technical (EPA Reg. No. 9468-45), per the Agency letter dated October 3, 2011.

In support of this submission, we submit the following:

1. Completed Application for Registration (EPA Form 8570-1)
2. One (1) copy of the Ritter Dicamba Technical final label
3. Letter of Authorization

Please contact me by telephone (253-853-7369) or e-mail (Ross@PyxisRC.com) if you have any questions or need any additional information.

Best regards,



Ross Gilbert

Enclosures

cc: Jaime Smith; Ritter Chemical, LLC



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 9468-45	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Ritter Chemicals, LLC/Ritter Dicamba Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Ritter Chemicals, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated <u>October 3, 2011</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of final product label per the Agency letter dated October 3, 2011.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) <u>Polypropylene woven bags</u>	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 800 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Ross Gilbert		Title Agent		Telephone No. (Include Area Code) (253)-853-7309	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent			
4. Typed Name Ross Gilbert		5. Date 12/13/2011			



Ritter Chemical LLC

October 28, 2009

To Whom It May Concern:

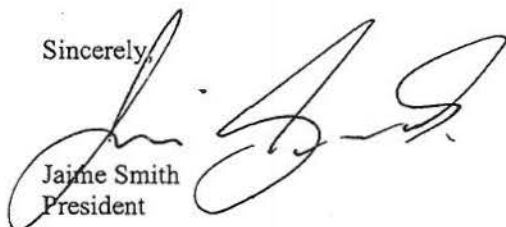
RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agents for Ritter Chemical, LLC (EPA Company Number 9468), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,



Jaime Smith
President

cc: Pyxis Regulatory Consulting, Inc.

Ritter Dicamba Technical
FOR MANUFACTURING HERBICIDES ONLY

ACTIVE INGREDIENT:
Dicamba [3,6-dichloro-o-anisic acid] 98.9%
OTHER INGREDIENTS: 1.1%
TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN
DANGER

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, Monday through Friday, 9 a.m. to 5 p.m. After 5:00 p.m., call your poison control center at 1-800-222-1222.	

EPA Reg. No. 9468-45
EPA Est. No.
Net Contents: See container

Manufactured for:
Ritter Chemical, LLC
P. O. Box 430974
Houston, TX 77243
(713) 461-2262

PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not contaminate water by the cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge

Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product may only be used to formulate herbicide products for the following use(s):

1. Asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, lawns, non-irrigation ditchbanks, rights-of-way, roadsides, turf and sod farms;
2. Uses for which EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
3. Uses for experimental purposes that are in compliance with EPA registration for the formulated products.

This product may be used to formulate products for specific uses not listed on the label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

Each formulator is responsible for obtaining EPA registration for their end-use product(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container, in a well-ventilated area away from fertilizers, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up, and collected for disposal. Wash area of spill with detergent and water.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Plastic Bag: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND LIABILITY

Ritter Chemical LLC warrants that this product conforms to the chemical description on the label, and is reasonably fit for the purposes set forth in the "Complete Directions for Use" booklet labeling, when used in accordance with those Complete Directions for Use, under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitation stated herein.

[20111003]

Material Sent for Data Extraction

Reg # 9468-45

Description: New Product

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 10/3/11

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☒ Decision #: 446591

☐ Other Action/Comments: _____

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: James Stone

Phone: 305-7391 Division: RD/HB

Date: 10/3/11



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg.

Number:

9468-45

Date of Issuance:

OCT - 3 2011

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Ritter Dicamba Tecnical

Name and Address of Registrant (include ZIP Code):

Ritter Chemical LLC
c/o Pyxis Regulatory Consulting, Inc.
4110 136th ST. NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product when the Agency requires all registrants of similar products to submit data.
2. Add the phrase "EPA Reg. No. 9468-45" to your label before you release the product for shipment.

Signature of Approving Official:

Kathryn V. Montague
Product Manager 23
Herbicide Branch
Registration Division (7505P)

Date:

OCT - 3 2011

page 2

EPA Reg. No. 9468-45

3. Submit one (1) copy of your final printed labeling before you release the product for shipment.

4. Submit the results of one year storage stability and corrosion characteristic studies to EPA within one year of this date of registration. Submit a hard copy and an electronic copy also.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Ritter Dicamba Technical

FOR MANUFACTURING HERBICIDES ONLY

ACTIVE INGREDIENT:Dicamba [3,6-dichloro-*o*-anisic acid]98.9%**OTHER INGREDIENTS:** 1.1%**TOTAL:**100.0%

KEEP OUT OF REACH OF CHILDREN

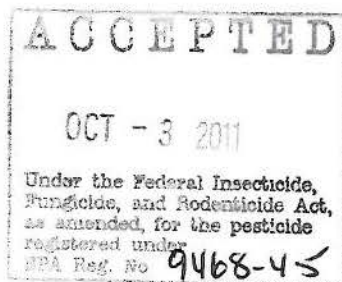
DANGER

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, Monday through Friday, 9 a.m. to 5 p.m. After 5:00 p.m., call your poison control center at 1-800-222-1222.	

See back panel for additional precautionary statements.

EPA Reg. No. 9468-
EPA Est. No.

Net Contents:



Manufactured for:
Ritter Chemical, LLC
P. O. Box 430974
Houston, TX 77243
(713) 461-2262

Batch No.:

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not contaminate water by the cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may only be used to formulate herbicide products for the following use(s):

1. Asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, lawns, non-irrigation ditchbanks, rights-of-way, roadsides, turf and sod farms;
2. Uses for which EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
3. Uses for experimental purposes that are in compliance with EPA registration for the formulated products.

This product may be used to formulate products for specific uses not listed on the label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

Each formulator is responsible for obtaining EPA registration for their end-use product(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container, in a well-ventilated area away from fertilizers, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up, and collected for disposal. Wash area of spill with detergent and water.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Plastic Bag: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND LIABILITY

Ritter Chemical LLC warrants that this product conforms to the chemical description on the label, and is reasonably fit for the purposes set forth in the "Complete Directions for Use" booklet labeling, when used in accordance with those Complete Directions for Use, under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitation stated herein.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

BARCODE: 388021; **Reg. No. /FILE SYMBOL No.:** 9468-UL; **PRODUCT:** Ritter Dicamba Technical

DATE: August 25, 2011

SUBJECT: Product Chemistry Review of "Ritter Dicamba Technical" TGA/MUP

FROM: Akiva Abramovitch, Ph.D.
Technical Review Branch / RD (7505P)

[Handwritten signature] *[Handwritten signature]* 9/7/11

TO: James Stone, Team Reviewer /Kathryne Montague, Risk Manager, RM 23
Herbicide Branch / RD (7505P)

DP BARCODE: 388021

DECISION No.: 446591

REGISTRATION NO./FILE SYMBOL NO.: 9468-UL

PRODUCT NAME: Ritter Dicamba Technical

PC CODE: 028801

REGISTRANT: Ritter Chemicals, LLC

USE: Herbicide

FOOD USE: Yes ☒ No ☐

MRID Numbers: 484205-01 through 484205-04

INTRODUCTION:

The registrant is seeking a new product registration for Ritter Dicamba Technical. The product is substantially similar (identical?) to a currently registered product [REDACTED] and the registrant is using the "cite-all" method of support. A basic formulation dated 9/6/11 (replaces the 3/11/11 CSF) was submitted as well as Group A data.

This review has been altered subsequent to the contractor's signatures.

SUMMARY OF FINDINGS:

1. The registrant submitted a Confidential Statement of Formula (CSF) for the basic formulation (3/11/2011). The product chemistry data corresponding to guideline reference 830.1550 (product identity & composition) submitted on the CSF satisfy the data requirements of 40CFR§158.155. The data corresponding to guideline reference 830.1750 (certified limits) satisfy the requirements of 40CFR§158.175 [MRID No. 484205-01]. The content of active ingredient given on the CSF for the basic formulation matches the label.
2. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160 [MRID No. 484205-01].
3. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40CFR§158.162 [MRID No. 484205-01].

Manufacturing process information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

BARCODE: 388021; **Reg. No. /FILE SYMBOL No.:** 9468-UL; **PRODUCT:** Ritter Dicamba Technical

4. The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion of the formation of impurities) satisfy the data requirements for 40CFR§158.167 [MRID No. 484205-01].
5. The product chemistry data submitted corresponding to guideline reference 830.1700 (preliminary analysis) to support the claims on the CSF satisfy the data requirements of 40CFR§158.170 [MRID No. 484205-02].
6. The product chemistry data submitted corresponding to guideline reference 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180 [MRID 484205-02].
7. The data submitted corresponding to guidelines 830 Series Subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR§158.190 [MRID No. 484205-03 and 484205-04]. Waivers were requested for explodability and flammability. Provision of corrosion characteristics and storage stability will be conducted if requested by the Agency.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for Ritter Dicamba Technical (produced by Ritter Chemicals, LLC) and has concluded that:

1. The product chemistry data submitted for guideline 830 Series group A are acceptable, except for impurities of potential concern.
2. The product chemistry data corresponding to 830 series group B (physical-chemical properties) are acceptable.
3. The proposed CSF for the basic formulation dated September 6, 2011 (replaces the March 11, 2011 CSF) is acceptable. The registrant listed all the known potential impurities of toxicological concern on the CSF. The total amount of unidentified impurities is at [REDACTED]
4. This product is substantially similar to product [REDACTED]. However, this product listed all potential toxic impurities on the CSF not listed on the "me-too" CSF. This product also has a higher percentage of unidentified residues [REDACTED] but none above 0.1%.

830.1550. Product identity & composition: (MRID No. 484205-01)

Common Name: Dicamba

Chemical name (CAS): 3,6-dichloro-2-methoxybenzoic acid

(IUPAC): 3,6-dichloro-*o*-anisic acid

CAS No.: 1918-00-9

PC Code No.: 028801

Empirical Formula: C₈H₆O₃Cl₂

Molecular Weight: 221.0

Structural Formula:

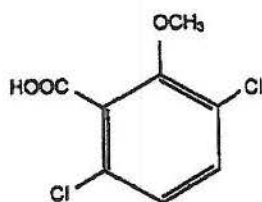


Table 1. Manufacturing and Impurity Data for Ritter Dicamba Technical TGA1				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	484205-01	A	CSF
830.1600	Description of materials used to produce the product	484205-01	A	
830.1620	Description of production process	484205-01	A	
830.1670	Discussion of formation of impurities	484205-01	U	potential impurities of toxicological concern were not identified or discussed.
830.1700	Preliminary analysis	484205-02	A	
830.1750	Certified limits	484205-01	A	
830.1800	Enforcement analytical method	484205-02	A	CSF
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ; U = Up-grade (additional information required);				

Manufacturing process information may be entitled to confidential treatment

830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of: Ritter Dicamba Technical TGA1				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	484205-03	A	Off-white with brown specks
830.6303	Physical state	484205-03	A	Solid crystals
830.6304	Odor	484205-03	A	Odorless
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	484205-03	A	Stable to normal and elevated temperatures for 14 days
830.6314	Oxidation/reduction: chemical incompatibility	484205-03	A	Compatible with water, hexane, zinc, $\text{NH}_4\text{H}_2\text{PO}_4$, and KMnO_4 .
830.6315	Flammability	484205-04, CSF	W	Solid; contains no flammable components
830.6316	Explosibility	484205-04	W	Solid; does not contain any explosive components
830.6317	Storage stability	484205-04	G	Will be conducted if requested by Agency
830.6319	Miscibility	484205-04	N/A	Not an emulsifiable liquid
830.6320	Corrosion characteristics	484205-04	G	Will be conducted if requested by Agency
830.7000	pH	484205-03	A	1.92 ± 0.03 at 25.7°C
830.7050	UV/Visible absorption	484205-03	A	Wavelength; molar absorption: Acid: $\lambda_{\text{max}} = 281.0$; $\epsilon_{\text{max}} = 776$ Neutral: $\lambda_{\text{max}} = 275.2$; $\epsilon_{\text{max}} = 490.3$ Basic: $\lambda_{\text{max}} = 275.$; $\epsilon_{\text{max}} = 469.7$
830.7100	Viscosity	484205-04	N/A	Solid
830.7200	Melting point	484205-03	A	$\sim 114.5 - 116.1^\circ\text{C}$
830.7220	Boiling point	484205-04	N/A	Solid
830.7300	Density	484205-03	A	0.702996 ± 0.000488 g/mL at 19°C
830.7370	Dissociation constants in water (DC)	484205-04	A	$\text{pK}_a = 1.97$ (Tomlin, The Pesticide Manual, 13 th Edition, p. 279, BCPC Publications, Hampshire, 2003)
830.7550	Partition coefficient (o/w)	484205-04	A	$\text{Log } P = -0.55$ (pH 5); -1.88 (pH 6.8); -1.9 (pH 8.9) (Tomlin, The Pesticide Manual, 13 th Edition, p. 279, BCPC Publications, Hampshire, 2003)
830.7840	Water solubility	484205-04	A	6.1 g/L at 25°C (Tomlin, The Pesticide Manual, 13 th Edition, p. 279, BCPC Publications, Hampshire, 2003)
830.7950	Vapor pressure	484205-04	A	1.67 mPa at 25°C (Tomlin, The Pesticide Manual, 13 th Edition, p. 279, BCPC Publications, Hampshire, 2003)
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ; U = Up-grade (additional information required); W = waivers				

830.1800 (enforcement analytical method)

The enforcement analytical method to determine the content of active ingredient is HPLC with UV detection. Appropriate validation and precision studies were conducted and sample chromatograms were provided. The registrant provided the following details in MRID 484205-01:

Ritter Dicamba Technical is dissolved in acetonitrile and separated on a ZORBAX XDB C8 reverse phase column. The content of dicamba is measured by an HPLC-UV detector with an external standard.

Apparatus

HPLC System:	Agilent 1100 HPLC
Glassware:	volumetric
Balance:	Mettler Toledo XS 205
Vials:	2 ml

Reagents

Dicamba standard:	known purity
Phosphoric Acid:	analytical grade
Acetonitrile:	HPLC grade
Water	redistilled

Chromatographic Conditions

Conditions may be changed to obtain satisfactory performance with other instruments provided adequate resolution and sensitivity are achieved.

Instrument:	Agilent 1100 HPLC
HPLC column:	ZORBAX XDB C8 150 x 4.6 mm, 5 micron
Mobile phase:	Acetonitrile/phosphoric acid aqueous solution (pH=3), 35:65
Column temperature:	25°C
Injection volume:	3 µl
Stop time:	8 minutes
Flow rate:	1.0 ml/min.
Wavelength:	230 nm
Retention time:	dicamba, ~ 5.3 minutes

DATA EVALUATION RECORD

DICAMBA (RITTER DICAMBA TECHNICAL)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
Description of Materials Used to Produce the Product (OPPTS 830.1600)
Description of the Production Process (OPPTS 830.1620)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRIDs 484205-01 through 484205-04

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Summitec Corporation
9724 Kingston Pike, Suite 602
Knoxville, Tennessee
Task Order No. 3-A-98

Primary Reviewer:
Thomas C. Marshall, Ph.D

Signature: Thomas C. Marshall,
Date: AUG 22 2011

Secondary Reviewers:
Dennis Opresko, Ph.D

Signature: Dennis Opresko,
Date: AUG 22 2011

Robert Ross, M.S., Program Manager

Signature: Robert W. Ross
Date: AUG 22 2011

Quality Assurance:
Angie Edmonds, B.S.

Signature: Angie Edmonds
Date: AUG 22 2011

Disclaimer

his review may have been altered subsequent to the contractor's signatures above.
Summitec Corp. for the U.S. Environmental Protection Agency under Contract No.EP-W-11-014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

**TECHNICAL REVIEW BRANCH
SIMILARITY DETERMINATION**

01/SEP/2011

MEMORANDUM

Subject: Name of Pesticide Product: Ritter Dicamba Technical
EPA Reg. No. /File Symbol: 9468-UL
DP Barcode: D388022
Decision No: 446591
Action Code: R310
PC Code: 029801 (dicamba)

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505P)

E. McAndrew
Harlie
Toxicologist

To: James Stone, RM Team 23
Herbicide Branch
Registration Division (7505P)

Applicant: Ritter Chemicals, LLC
P.O. Box 430974
Houston, TX 77243

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Dicamba	98.9
<u>Other Ingredient(s):</u>	<u>1.1</u>
Total:	100.0%

EPA File Symbol 9468-UL
PC Code 029801 (dicamba)

ACTION REQUESTED: The Risk Manager requests: For Similarity Clinic: "Under the Cite-All Method is the acute toxicity substantially similar to the cited me too product [REDACTED]"

BACKGROUND: Ritter Chemicals, LLC has applied for registration of Ritter Dicamba Technical, EPA File Symbol 9468-UL, claiming similarity to [REDACTED]

[REDACTED] Both products are technical grade for manufacturing use only. The registrant is using the cite-all method of data support to satisfy the acute toxicity data requirements. A basic CSF dated March 11, 2011, a label and company letter are included in the submission.

A search of the OPP electronic databases shows that [REDACTED]

RECOMMENDATIONS:

1. TRB compared the formulations of the proposed product, 9468-UL and the cited product, [REDACTED] and concluded that the two products are substantially similar.
2. The acute toxicity profile for the proposed product, Ritter Dicamba Technical, EPA File Symbol 9468-UL, is as follows:

acute oral toxicity	III	cited
acute dermal toxicity	IV	cited
acute inhalation toxicity	IV	cited
primary eye irritation	I	cited
primary skin irritation	IV	cited
dermal sensitization	negative	cited

3. This memorandum pertains only to the decision concerning whether the subject product is similar to the cited product from an acute toxicological view point. For the purposes of this action, TRB has made no further determination of the adequacy of the toxicological data base or the precautionary label of the cited product.

4. The proposed basic CSF submitted for 9468-UL must be accepted by the TRB Product Chemistry Team.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 009468-00045

PRODUCT NAME: Ritter Dicamba Technical

PRECAUTIONARY STATEMENTS

SIGNAL WORD: DANGER

Hazards to Humans and Domestic Animals:

Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses).

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

User Safety Recommendations:

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

DATA PACKAGE BEAN SHEET

Date: 25-Mar-2011

Page 1 of 2

Decision #: 446591

DP #: (388021)

PRIA

Parent DP #:

Submission #: 892170

*** Registration Information ***

Registration: 9468-UL - RITTER DICAMBA TECHNICAL

Company: 9468 - RITTER CHEMICAL, LLC

Risk Manager: RM 23 - Kathryn Montague - (703) 305-1243 Room# PY1 S-7332

Risk Manager Reviewer: James Stone JSTONE

Sent Date:

Calculated Due Date: 06-Jul-2011

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (~~NEW~~) NEW PRODUCT; ME-TOO PRODUCT FAST TRACK;

Ingredients: 029801, Dicamba(98.9%)

R310
28623

OCT, 2011

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 25-Mar-2011

Due Back:

DP Ingredient: 029801, Dicamba

DP Title:

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 22-May-2011

Team Name: CHEM

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

Sept 6, 11

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Review product chemistry data for new unregistered technical dicamba product.

MRID	MRID Status	Citation Reference	Guideline
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.7520/Particle size, fiber length, and diameter distribution
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.6319/Miscibility
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.6315/Flammability
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.7550/Partition coefficient (n-octanol/water), shake flask method
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.7220/Boiling point/boiling range
48420501		Tillman, A. (2011) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Ritter Dicamba Technical. Project Number: RC/201006. Unpublished study prepared by Ritter Chemicals, LLC. 155 p.	830.1600/Description of materials used to produce the product
48420503		Weller, P. (2011) Group B - Product Chemistry Analysis of Dicamba Technical. Project Number: 311100/1/001. Unpublished study prepared by MRIGlobal. 37 p.	830.7200/Melting point/melting range
48420501		Tillman, A. (2011) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Ritter Dicamba Technical. Project Number: RC/201006. Unpublished study prepared by Ritter Chemicals, LLC. 155 p.	830.1550/Product Identity and composition
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.6313/Stability to normal and elevated temperatures, metals, and metal ions
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.7100/Viscosity
48420501		Tillman, A. (2011) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Ritter Dicamba Technical. Project Number: RC/201006. Unpublished study prepared by Ritter Chemicals, LLC. 155 p.	830.1620/Description of production process
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.7370/Dissociation constants in water
48420503		Weller, P. (2011) Group B - Product Chemistry Analysis of Dicamba Technical. Project Number: 311100/1/001. Unpublished study prepared by MRIGlobal. 37 p.	830.7000/pH

MRID	MRID Status	Citation Reference	Guideline
48420502		Li, H. (2011) Preliminary Analysis and Enforcement Analytical Method of Dicamba TGA1 - Validation of Analytical Methodology for the Assay of Active Ingredient and Related Significant Impurities and Subsequent 5-Batch Analysis of Dicamba TGA1. Project Number: NC/2007/024. Unpublished study prepared by Nutrichem Laboratory Co., Ltd. 91 p.	
48420503		Weller, P. (2011) Group B - Product Chemistry Analysis of Dicamba Technical. Project Number: 311100/1/001. Unpublished study prepared by MRIGlobal. 37 p.	830.6313/Stability to normal and elevated temperatures, metals, and metal ions
48420503		Weller, P. (2011) Group B - Product Chemistry Analysis of Dicamba Technical. Project Number: 311100/1/001. Unpublished study prepared by MRIGlobal. 37 p.	830.7050/UV/Visible absorption
48420503		Weller, P. (2011) Group B - Product Chemistry Analysis of Dicamba Technical. Project Number: 311100/1/001. Unpublished study prepared by MRIGlobal. 37 p.	830.6304/Odor
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.7300/Density/relative density
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.7950/Vapor pressure
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.7860/Water solubility, generator column method
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.7560/Partition coefficient (n-octanol/water), generator column method
48420503		Weller, P. (2011) Group B - Product Chemistry Analysis of Dicamba Technical. Project Number: 311100/1/001. Unpublished study prepared by MRIGlobal. 37 p.	830.6303/Physical state
48420501		Tillman, A. (2011) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Ritter Dicamba Technical. Project Number: RC/201006. Unpublished study prepared by Ritter Chemicals, LLC. 155 p.	830.1750/Certified limits
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.6320/Corrosion characteristics
48420503		Weller, P. (2011) Group B - Product Chemistry Analysis of Dicamba Technical. Project Number: 311100/1/001. Unpublished study prepared by MRIGlobal. 37 p.	830.6314/Oxidizing or reducing action
48420503		Weller, P. (2011) Group B - Product Chemistry Analysis of Dicamba Technical. Project Number: 311100/1/001. Unpublished study prepared by MRIGlobal. 37 p.	830.7300/Density/relative density
48420501		Tillman, A. (2011) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Ritter Dicamba Technical. Project Number: RC/201006. Unpublished study prepared by Ritter Chemicals, LLC. 155 p.	830.1800/Enforcement analytical method
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.6321/Dielectric breakdown voltage
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.6316/Explosibility
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.6317/Storage stability
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.7570/Partition coefficient (n-octanol/water), estimation by liquid chromatography
48420501		Tillman, A. (2011) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Ritter Dicamba Technical. Project Number: RC/201006. Unpublished study prepared by Ritter Chemicals, LLC. 155 p.	830.1670/Discussion of formation of impurities
48420504		Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	830.7840/Water solubility: Column elution method, shake flask method
48420503		Weller, P. (2011) Group B - Product Chemistry Analysis of Dicamba Technical. Project Number: 311100/1/001. Unpublished study prepared by MRIGlobal. 37 p.	830.6302/Color

DATA PACKAGE BEAN SHEET

Date: 25-Mar-2011

Page 1 of 1

Decision #: 446591

DP #: (388022)

PRIA

Parent DP #:

Submission #: 892170

*** Registration Information ***

Registration: 9468-UL - RITTER DICAMBA TECHNICAL

Company: 9468 - RITTER CHEMICAL, LLC

Risk Manager: RM 23 - Kathryn Montague - (703) 305-1243 Room# PY1 S-7332

Risk Manager Reviewer: James Stone JSTONE

Sent Date:

Calculated Due Date: 06-Jun-2011

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (B200) NEW PRODUCT; ME-TOO PRODUCT FAST TRACK;

Ingredients: 029801, Dicamba(98.9%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 25-Mar-2011

Due Back:

DP Ingredient: 029801, Dicamba

DP Title:

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 22-May-2011

Team Name: TOX

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

For Similarity Clinic

Under the Cite-All Method is the acute toxicity substantially similar to the cited me too product

Product ingredient source information may be entitled to confidential treatment

PYXIS REGULATORY CONSULTING, INC.

484205-00

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

March 11, 2011

OVERNIGHT DELIVERY

Kathryn Montague (PM 23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Ritter Chemical, LLC
Ritter Dicamba Technical (EPA File Symbol 9468-)
Application for New Pesticide Registration
PRIA category R310 (46: New manufacturing use product)

Dear Ms. Montague,

On behalf of Ritter Chemical, LLC, we are submitting an application for registration of Ritter Dicamba Technical. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Three (3) Copies of the Proposed Labeling
4. A CD containing an electronic version of the proposed labeling
5. Certification with Respect to Label Integrity
6. Certification with Respect to Citation of Data (EPA Form 8570-34)
7. Agency Internal Use Copy of the Data Matrix
8. Public File Copy of the Data Matrix
9. Copy of PRIA payment
10. Letter of Authorization
11. Product Specific Data (3 copies of each report):

48420501

Volume 1	830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750, 830.1800	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Description of the Formulation Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Ritter Dicamba Technical. <i>Contains Confidential Business Information.</i>
Volume 2	830.1700, 830.1800	Li, H. Preliminary Analysis and Enforcement Analytical Method of Dicamba TGAI. <i>Contains Confidential Business Information.</i>

48420502

48420503

Volume 3	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.7000, 830.7050, 830.7200, 830.7300	Weller, P. J. Group B Product Chemistry Analysis of Dicamba Technical.
Volume 4	830.6313, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7100, 830.7220, 830.7300, 830.7370, 830.7520, 830.7550-7570, 830.7840-7860, 830.7950	Tillman, A. M. Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties.

48420504

We would like to note that Ritter Chemical, LLC is using the cite-all method of support. As per EPA's interpretations of 40 CFR Parts 152.86(b)(2)(i) and 152.93(b)(2)(i), Ritter Chemical, LLC submitted notices of intent to apply and offers to pay to all companies on the September 30, 2010 Data Submitter's List. This action falls under PRIA category R310 (46: New manufacturing use product) because it is an application for registration for a manufacturing use product identical to a currently registered product. The PRIA fee for this action is \$4,807 and has been paid. The decision timeline is 6 months.

We trust you will find this application complete. However, please feel free to contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

File com

March 28, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-446591
EPA File Symbol or Registration Number: 9468-UL
Product Name: RITTER DICAMBA TECHNICAL
EPA Receipt Date: 16-Mar-2011
EPA Company Number: 9468
Company Name: RITTER CHEMICAL, LLC

Ann Tillman
PYXIS REGULATORY CONSULTING, INC.
RITTER CHEMICAL, LLC
4110 136TH STREET, N.W.,
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action previously identified as R300 has been reclassified identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,
Front End Processing Staff
Information Technology & Resources Management Division

Jim Storo



Fw: Ritter Dicamba Technical 9468-UL PRIA Category
Stephen Schaible to: John Jamula, Teresa Downs

03/25/2011 04:40 PM

JJ,

Please recode this action as an R310. Thanks! Steve

Stephen A. Schaible
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460
ph: (703)308-9362
fax: (703)305-6920

----- Forwarded by Stephen Schaible/DC/USEPA/US on 03/25/2011 04:39 PM -----

From: Ann Tillman <Ann@PyxisRC.com>
To: Stephen Schaible/DC/USEPA/US@EPA
Cc: Teresa Downs/DC/USEPA/US@EPA
Date: 03/24/2011 10:38 AM
Subject: RE: Ritter Dicamba Technical 9468-UL PRIA Category

Thanks, Steve. This application is not a 100% repack.

Ann

-----Original Message-----

From: Schaible.Stephen@epamail.epa.gov [mailto:Schaible.Stephen@epamail.epa.gov]
Sent: Thursday, March 24, 2011 10:32 AM
To: Ann Tillman
Cc: Downs.Teresa@epamail.epa.gov
Subject: Re: Ritter Dicamba Technical 9468-UL PRIA Category

Hi Ann,

At face value, I would absolutely agree. The only situation where a technical would qualify as a R300 would be if it is a 100% repack. It sounds like this was a coding error on our end, and I'll follow up with Teresa and JJ to make sure this is the case.

Thanks for bringing this to my attention! In all likelihood this would have been caught once it got to the PM, but you are getting clarity earlier in the process this way.

Regards, Steve

Stephen A. Schaible
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460
ph: (703)308-9362
fax: (703)305-6920

From: Ann Tillman <Ann@PyxisRC.com>
To: Stephen Schaible/DC/USEPA/US@EPA
Date: 03/24/2011 06:53 AM
Subject: Ritter Dicamba Technical 9468-UL PRIA Category

Hi, Steve,

I received this letter (attached) in the mail but I really don't believe that the PRIA category should be R300. Every application for registration of a me-too technical has typically been R310. Is there something different about this application that makes it an R300?

Ann

Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com

[attachment "20110317 9468-UL PRIA reclassification.pdf" deleted by Stephen Schaible/DC/USEPA/US]

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95

 <div style="text-align: center;"> United States Environmental Protection Agency Washington, DC 20460 </div>	<div style="border: 1px solid black; padding: 2px;"> <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other </div>	OPP Identifier Number
---	---	-----------------------

Application for Pesticide - Section I

1. Company/Product Number 9468- <u>LL</u>	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Ritter Chemicals, LLC/Ritter Dicamba Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Ritter Chemicals, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. XXXXXXXXXX Product Name XXXXXXXXXX

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input checked="" type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
---	--


Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under Category R310 (46: New manufacturing use product) because it is an application for registration for a new technical product identical in composition to a currently registered product. The fee which is due is \$4,807.00 and has been paid. The decision timeline is 6 months.

Section - III

1. Material This Product Will Be Packaged In:						2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No				<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) <u>Polypropylene woven bags</u>	
<i>* Certification must be submitted</i>		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 800 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product			
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____							

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Pyxis Regulatory Consulting, Inc.	Title Agent	Telephone No. (Include Area Code) (253)-853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. - I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Agent		
4. Typed Name Ann M. Tillman	5. Date <u>3/11/11</u>		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Ritter Chemicals, LLC c/o Pyxis Regulatory 4110 136th St. NW Gig Harbor, WA 253- 853-7369	EPA Registration Number/File Symbol 9468-
Active Ingredient(s) and/or representative test compound(s) Dicamba	Date 3/11/11
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial food/feed, Terrestrial Non-food, Residential Outdoor	Product Name Ritter Dicamba Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Ann M. Tillman

Date

3/11/11

Typed or Printed Name and Title


Ann M. Tillman, Agent

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX


Date March 7, 2011			EPA Reg. No./File Symbol 9468-		Page 1 of 7
Applicant's/Registrant's Name & Address Ritter Chemical, LLC P.O. Box 430974 Houston, TX 77243			Product Ritter Dicamba Technical		
Ingredient Dicamba (CAS No. 1918-00-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	Volume 1	Ritter Chemical, LLC	OWN	
830.1600	Description of Materials Used to Produce the Product	Volume 1	Ritter Chemical, LLC	OWN	
830.1620	Description of Production Process	Volume 1	Ritter Chemical, LLC	OWN	
830.1650	Description of Formulation Process				Not required ¹
830.1670	Discussion of Formation of Impurities	Volume 1	Ritter Chemical, LLC	OWN	
830.1700	Preliminary Analysis	Volume 2	Ritter Chemical, LLC	OWN	
830.1750	Certified Limits	Volume 1	Ritter Chemical, LLC	OWN	
830.1800	Enforcement Analytical Method	Volume 1 Volume 2	Ritter Chemical, LLC Ritter Chemical, LLC	OWN OWN	
830.6302	Color	Volume 3	Ritter Chemical, LLC	OWN	
830.6303	Physical State	Volume 3	Ritter Chemical, LLC	OWN	
830.6304	Odor	Volume 3	Ritter Chemical, LLC	OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date March 7, 2011

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401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date March 7, 2011			EPA Reg. No./File Symbol 9468-		Page 2 of 7
Applicant's/Registrant's Name & Address Ritter Chemical, LLC P.O. Box 430974 Houston, TX 77243			Product Ritter Dicamba Technical		
Ingredient Dicamba (CAS No. 1918-00-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Volume 3 Volume 4	Ritter Chemical, LLC Ritter Chemical, LLC	OWN OWN	Data Waiver ²
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volume 3	Ritter Chemical, LLC	OWN	
830.6315	Flammability	Volume 4	Ritter Chemical, LLC	OWN	Waiver ³
830.6316	Explodability	Volume 4	Ritter Chemical, LLC	OWN	Waiver ⁴
830.6317	Storage Stability	Volume 4	Ritter Chemical, LLC	OWN	PRN 92-5 ⁵
830.6319	Miscibility	Volume 4	Ritter Chemical, LLC	OWN	Waiver ⁶
830.6320	Corrosion Characteristics	Volume 4	Ritter Chemical, LLC	OWN	PRN 92-5 ⁵
830.6321	Dielectric Breakdown Voltage	Volume 4	Ritter Chemical, LLC	OWN	Not required ⁷
830.7000	pH	Volume 3	Ritter Chemical, LLC	OWN	
830.7050	UV/Visible Absorption	Volume 3	Ritter Chemical, LLC	OWN	
830.7100	Viscosity	Volume 4	Ritter Chemical, LLC	OWN	Not required ⁷
830.7200	Melting Point/Melting Range	Volume 3	Ritter Chemical, LLC	OWN	
830.7220	Boiling Point/Boiling Range	Volume 4	Ritter Chemical, LLC	OWN	Not required ⁸
Signature 			Name and Title Ann M. Tillman, Consultant		Date March 7, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date March 7, 2011

EPA Reg. No./File Symbol 9468-

Page 3 of 7

Applicant's/Registrant's Name & Address

Ritter Chemical, LLC
P.O. Box 430974
Houston, TX 77243

Product

Ritter Dicamba Technical

Ingredient Dicamba (CAS No. 1918-00-9)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density/Relative Density/Bulk Density	Volume 3	Ritter Chemical, LLC	OWN	See endnote ⁹
830.7370	Dissociation Constants in Water	Volume 4	Ritter Chemical, LLC	PL	
830.7520	Particle Size, Fiber Length, and Diameter Distribution	Volume 4	Ritter Chemical, LLC	OWN	Waiver ¹⁰
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	Volume 4	Ritter Chemical, LLC	PL	
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	Volume 4	Ritter Chemical, LLC	PL	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	Volume 4	Ritter Chemical, LLC	PL	

Signature



Name and Title

Ann M. Tillman, Consultant

Date


March 7, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date March 7, 2011			EPA Reg. No./File Symbol 9468-		Page 4 of 7
Applicant's/Registrant's Name & Address Ritter Chemical, LLC P.O. Box 430974 Houston, TX 77243			Product Ritter Dicamba Technical		
Ingredient Dicamba (CAS No. 1918-00-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity: Rat	Cite-All		PAY	
870.1200	Acute Dermal Toxicity: Rat	Cite-All		PAY	
870.1300	Acute Inhalation Toxicity: Rat	Cite-All		PAY	
870.2400	Primary Eye Irritation: Rabbit	Cite-All		PAY	
870.2500	Primary Dermal Irritation	Cite-All		PAY	
870.2600	Dermal Sensitization	Cite-All		PAY	
Dicamba Product Specific and Generic Data Requirements					
Ritter Chemical, LLC is using the cite-all option to satisfy product specific and generic data requirements will make offers-to-pay to the following companies on the dicamba data submitters list of September 30, 2010.					
		Cite-All	Syngenta Crop Protection, Inc.	PAY	
		Cite-All	Nufarm Americas Inc.	PAY	
		Cite-All	BASF Corp.	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date March 7, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date March 7, 2011			EPA Reg. No./File Symbol 9468-		Page 5 of 7
Applicant's/Registrant's Name & Address Ritter Chemical, LLC P.O. Box 430974 Houston, TX 77243			Product Ritter Dicamba Technical		
Ingredient Dicamba (CAS No. 1918-00-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	E. I. DuPont de Nemours and Co., Inc.	PAY	
		Cite-All	Bayer Environmental Science	PAY	
		Cite-All	Monsanto Co.	PAY	
		Cite-All	The Scotts Co.	PAY	
		Cite-All	PBI/Gordon Corp.	PAY	
		Cite-All	BASF Corp.	PAY	
		Cite-All	The Andersons Lawn Fertilizer Division	PAY	
		Cite-All	Chemisco	PAY	
		Cite-All	Loveland Products, Inc.	PAY	
		Cite-All	Albaugh, Inc.	PAY	
		Cite-All	Dow Agrosciences LLC	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	W. Neudorff GmbH Kg	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date March 7, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date March 7, 2011

EPA Reg. No./File Symbol 9468-

Page 6 of 7


Applicant's/Registrant's Name & Address

Ritter Chemical, LLC
P.O. Box 430974
Houston, TX 77243

Product

Ritter Dicamba Technical


Ingredient Dicamba (CAS No. 1918-00-9)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Repar Corp.	PAY	
		Cite-All	Petro-Canada Lubricants Inc.	PAY	
		Cite-All	Gharda USA, Inc.	PAY	
		Cite-All	Nufarm, Inc.	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	Bayer Advanced	PAY	
		Cite-All	FIFRA Endangered Species Task Force LLC	PAY	
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	Agricultural Handlers Exposure Task Force	PAY	
Signature			Name and Title		Date
			Ann M. Tillman, Consultant		March 7, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date March 7, 2011			EPA Reg. No./File Symbol 9468-		Page 7 of 7
Applicant's/Registrant's Name & Address Ritter Chemical, LLC P.O. Box 430974 Houston, TX 77243			Product Ritter Dicamba Technical		
Ingredient Dicamba (CAS No. 1918-00-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Libertas Now, Inc.	PAY	
		Cite-All	J. Oliver Products, LLC	PAY	
		Cite-All	Tacoma Ag, LLC	PAY	
		Cite-All	Gharda Generics, Inc.	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date March 7, 2011

Endnotes for Data Matrix for Ritter Dicamba MUP

-
- ¹ **830.1650** - These data are not required for the registration of a technical product. See 830.1620 for production process information.
- ² **830.6313** - Ritter Chemical, LLC requests a waiver from the stability to metal and metal ion portion of this data requirement. Ritter Chemical, LLC does not intend to package Dicamba Technical in metal containers, nor is Dicamba Technical expected to come into contact with metals or metal ions during its storage or use. Therefore, a waiver from the requirement of these data is requested. Dicamba Technical was found to be stable at normal and elevated temperatures (these data are reported separately and is part of this submission).
- ³ **830.6315** - Ritter Chemical, LLC requests a waiver from the requirement of this data requirement since Dicamba Technical is a solid and does not contain any ingredients that are flammable. Please refer to the Confidential Statement of Formula for Dicamba Technical.
- ⁴ **830.6316** - Ritter Chemical, LLC requests a waiver from this data requirement. Dicamba does not have the chemical bonds or functional groups associated with explosive chemicals.
- ⁵ **830.6317, 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Ritter Chemical, LLC has initiated these studies and will submit the final report when available.
- ⁶ **830.6319** - This data requirement is required when the MUP is an emulsifiable liquid and to be diluted with petroleum solvents. Ritter Dicamba Technical is not an end-use product. Therefore these data are not required for Ritter Dicamba Technical.
- ⁷ **830.6321, 830.7100** - Dielectric breakdown data are required if the product is an end-use product. This data requirement is not applicable Ritter Dicamba Technical. Viscosity is required for liquid products and is not applicable to the solid Ritter Dicamba Technical.
- ⁸ **830.7220** - This data requirement is not applicable to Ritter Dicamba Technical because it is a solid. Refer to guideline 830.7200 for melting point data.
- ⁹ **830.7300** - Ritter Chemical, LLC conducted bulk density with Ritter Dicamba Technical. The bulk density is 0.703 g/mL. The public literature density for dicamba acid is reported to be 1.488 (Ref. (Reference: Tomlin, "The Pesticide Manual", 13th Edition, p. 279, BCPC Publications, Hampshire, 2003). However, EPA documents (docket EPA-HQ-OPP-2005-0479-005) indicate that the relative density is 1.57 which was obtained from a technical material that was only 87% pure. EPA cited data from the 6/30/89 Reregistration Standard. The bulk density of the Ritter Dicamba Technical me-too technical dicamba acid must be similar to the value obtained for Ritter Dicamba Technical: Tacoma Ag, LLC's Dicamba Acid Technical, EPA Reg. No. 83520-8, is also a me-too of the same cited product (based on information in the Registration Jacket for 83520-8) and the bulk density of the Tacoma Ag, LLC's technical product is 0.608 g/mL (see MSDS in Attachment 1). The bulk density values for Ritter Dicamba Technical and Tacoma Ag LLC's technical are similar. Therefore, the bulk density for Ritter Dicamba Technical should not be compared to data in the public literature since that data is for relative density and from an 87% pure technical material.
- ¹⁰ **830.7520** - Ritter Chemical, LLC is seeking a waiver for this data requirement. Ritter Dicamba Technical is not a fibrous material nor is it water insoluble.

R 300 and 301

100% identical (repack): YES or NO (circle one)

{If **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group and A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition	X	
830.1600	Description of materials used to produce the product	X	
830.1650	Description of formulation process		X
830.1670	Discussion on the formation of impurities	X	
830.1700	Preliminary analysis	X	
830.1750	Certified limits (158.345)	X	
830.1800	Enforcement analytical method	X	

NR

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color	X	
830.6303	Physical State	X	
830.6304	Odor	X	
830.6314	Oxidation/Reduction (Chemical incompatibility)	X	
830.6315	Flammability		X
830.6316	Explosibility		X
830.6317	Storage stability		X
830.6319	Miscibility		X
830.6320	Corrosion Characteristics		X
830.6321	Dielectric Breakdown voltage		X
830.7000	pH	X	
830.7100	Viscosity		X
830.7300	Density	X	

waiver

waiver

in progress

NR

in progress

NR

NR

R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)	X	
870.1200	Acute Dermal (LD50)	X	
870.1300	Acute Inhalation (LC50)	X	
870.2400	Acute Eye Irritation	X	
870.2500	Acute Dermal Irritation	X	
870.2600	Dermal Sensitization	X	

Efficacy – which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants			NA
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments			NA
810.3300	Treatments to Control Pests of Humans and Pets			NA
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments			NA
810.3500	Premises Treatments			NA
810.3600	Structural Treatments			NA
810.3800	Methods for Efficacy Testing of Termite Baits			NA

21-Day Screen Completed by
Contractor

21-Day Expires on 4-6-11

Jacket # 9468-UL

MRID# 484205

Content Screen: Recommend to Pass/Fail

86-5 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Stephen Schable

PM 23

Y

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 3-16-11 ^{3/23/09}

Experts In-Processing Signature: B. R. Date 3-18-11 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>9468-UL</u>		EPA Receipt Date: <u>3-16-11</u>								
Items for Review				Yes	No	N/A*				
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X						
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X						
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center;">yes</th> <th style="text-align: center;">no</th> </tr> <tr> <td style="text-align: center;">No inerts</td> <td></td> </tr> </table>	yes	no	No inerts				
yes	no									
No inerts										
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X						
	Certificate and data matrix consistent			X						
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center;">yes</th> <th style="text-align: center;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no									
	If applicable, is there a letter of Authorization for exclusive use only.									
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X				
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X						
	a) Selective Method (Fee category experts use)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center;">yes</th> <th style="text-align: center;">no</th> </tr> <tr> <td style="text-align: center;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no									
X										
	b) Cite-All (Fee category experts use)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center;">yes</th> <th style="text-align: center;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no									
	c) Applicant owns all data (Fee category experts use)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center;">yes</th> <th style="text-align: center;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no									
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X						

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- * No inerts for review. Active & impurities only.
- * In Study #1, pg 49 was missing and pages 134 & 135 were missing data. The registrant sent the corrected pages when contacted. Thus all the studies submitted along with this submission has passed the PRN 86-5 Review.

Studies passed
Label passed

AB

MRID : 484205

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



RE: Submission to EPA: Product Ritter Dicamba Technical (EPA Reg# 9468-UL)

Ann Tillman to: Aswathy Balan

03/21/2011 02:29 PM

Aswathy, that is fine. I will make a note that you made that change.

Ann

-----Original Message-----

From: Balan.Aswathy@epamail.epa.gov [mailto:Balan.Aswathy@epamail.epa.gov]

Sent: Monday, March 21, 2011 2:24 PM

To: Ann Tillman

Subject: RE: Submission to EPA: Product Ritter Dicamba Technical (EPA Reg# 9468-UL)

Ms. Ann, I am putting an "Intentionally left blank" page as page number 134 and the MSDS you sent me will be pages 135-139 so that the page count of your study will not be altered and remain as 139 pages in confidential attachment. Let me know whether this is okay with you.

Aswathy Balan
Macfadden, EPA Contractor
2777 S. Crystal Drive, S4810
Arlington, VA 22202
Ph: 703-347-8787
Fax: 703-305-5060

From: Ann Tillman <Ann@PyxisRC.com>
To: Aswathy Balan/DC/USEPA/US@EPA
Cc: Sree Nair/DC/USEPA/US@EPA
Date: 03/21/2011 01:58 PM
Subject: RE: Submission to EPA: Product Ritter Dicamba Technical (EPA Reg# 9468-UL)

Aswathy,

Attached is page 49 from Volume 1. I checked pages 134 and 135 and I realized that there must have been an error in the copy/paste when I inserted the MSDS into the original Word document and I did not catch that in the final version of the report. The information on pages 135 and 136 should have been on page 134 but somehow the information was separated. The information for Section 1 of the MSDS is found on page 136 beginning with the Company Identification. A copy of the MSDS is attached so you can see that no information is missing.

Ann

-----Original Message-----

From: Balan.Aswathy@epamail.epa.gov [mailto:Balan.Aswathy@epamail.epa.gov]

Sent: Monday, March 21, 2011 1:27 PM

To: Ann Tillman

Cc: Nair.Sree@epamail.epa.gov

Subject: Submission to EPA: Product Ritter Dicamba Technical (EPA Reg#

9468-UL)

Dear Ms. Tillman,

This is a follow-up email regarding your Application for Registration of the product Ritter Dicamba Technical (EPA Reg# 9468-UL). We have found some issues regarding your application.

In Study #1: From the confidential attachment page 49 is missing and data is missing from pages 134 and 135(these pages look incomplete).

You can send the corrected pages either by fax to 703-305-5060, Attn: Aswathy Balan or email to balan.aswathy@epa.gov. Please call me back at 703-347-8787 if you have any questions.

Thanks,

Aswathy Balan
Macfadden, EPA Contractor
2777 S. Crystal Drive, S4810
Arlington, VA 22202
Ph: 703-347-8787
Fax: 703-305-5060

[attachment "20110311 Ritter Dicamba Tech Application Package Vol. 1_missing page.pdf" deleted by Aswathy Balan/DC/USEPA/US] [attachment "MSDS for [REDACTED].pdf" deleted by Aswathy Balan/DC/USEPA/US]

Manufacturing process information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 17, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-446591
EPA File Symbol or Registration Number: 9468-UL
Product Name: RITTER DICAMBA TECHNICAL
EPA Receipt Date: 16-Mar-2011
EPA Company Number: 9468
Company Name: RITTER CHEMICAL, LLC

JANELLE KAY
PYXIS REGULATORY CONSULTING, INC.
RITTER CHEMICAL, LLC
4110 136TH STREET, N.W,
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300

NEW PRODUCT;ME-TOO PRODUCT FAST TRACK;

No additional payment is due at this time. We will process a refund of your \$3,373 overpayment as soon as is practicable.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely, *Beressa Downs*
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

M
{892170É~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

23

Receipt No.

S-

892170

EPA File Symbol/Reg. No.

9468-UL

Pin-Punch Date:

3/16/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R310

Granted:

R300

Amount Due: \$ 1434⁰⁰

Active & impurities only. AB 03/18/11

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: *Divmont*

Date: 3/17/11

Remarks:

Receipt for Section 3			
S: 892170	Resubmission: <input type="radio"/> Yes <input checked="" type="radio"/> No		<div>Print Letter</div> <div>Enter More Information</div> <div>Tracking</div>
Regulatory Type: Product Registration - Section 3	Fee For Service: <input checked="" type="radio"/> Yes <input type="radio"/> No		
Application Type: New Registration	Billable: <input checked="" type="radio"/> Yes <input type="radio"/> No		
Company: 9468 RITTER CHEMICAL, LLC	V		
Risk Manager: Registration Division, Risk Management Team 23			
Product #: 9468-UL	Product Name: RITTER DICAMBA TECHNICAL		
Override#:			
Me Too Section3:	Me Too Product Name:		
Application Date: 11-Mar-2011	OPP Rec'd Date: 16-Mar-2011	<div>Receipt Content</div> <div>Study</div> <div>CSF</div> <div>View/Edit</div>	
Front End Date: 16-Mar-2011	Risk Manager Send Date:		
FFS Due Date:	Negotiated Due Date:		
OPP Target Date:			
Fast Track: <input type="checkbox"/>	New Ingredient: <input type="checkbox"/>		
Receipt Description: New registration		New Ingredient Request Date:	
		New Ingredient Received Date:	
Form A: <input type="checkbox"/>	Signature Date:	Form B: <input type="checkbox"/>	Signature Date:

FEE FOR SERVICE

Sarah Greubel

From: paygovadmin@mail.doc.twai.gov
Sent: Monday, March 14, 2011 3:06 PM
To: Sarah Greubel
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 252R8C4L
Agency Tracking ID: 74183880854
Transaction Type: Sale
Transaction Date: Mar 14, 2011 6:05:31 PM

Account Holder Name: Ann Tillman
Transaction Amount: \$4,807.00
Billing Address: 4110 136th St NW
City: Gig Harbor
State/Province: WA
Zip/Postal Code: 98332
Country: USA
Card Type: AmericanExpress
Card Number: *****1031

Decision Number:
Registration Number:
Company Name: Ritter Chemical LLC
Company Number: 9468
Action Code: R310

Decision Information for 9468-UL

Decision Seq: 448591 Action Code: R300, NEW PRODUCT; ME-TOO PRODUCT FAST TRACK; 90

FFS Start Date: 06-Apr-2011 Tentative Ind: No FFS Original Decision: ...

Due Date: 06-Jul-2011 75-Day Due Date: ... FFS EUP Decision: ...

OPP Target Due Dt: ... 21-Day Screen Dt: 06-Apr-2011 FFS Primary Decision: ...

Negotiated Due Dt: ... Start/Stop Clock: FQPA Clock: ...

Registrant: ... Days Elapsed: ...

Response Due Date: ...

Current Status: PENDING (17-Mar-2011)

Decision Comments Payment Unmatched Payments 75 Day Letters

Meetings & Milestones FFS Information FFS Negotiated Due Dates OPP Target Due Date

Decision Ownership Receipts Data Package Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 892170	Stone, James	9468-UL	06-Jul-2011	PENDING

NA

Viewing Record 1 of 1

(R300) due 7/6/11

3/28/11

Hi, Jim,

New product - has pchem data,
(cite-all)
Citing acute tox - needs similarity
review. Technical dicamba product.

Thanks,
Kay

9468-UL

R300

Memorandum

Needs
Admin

KM
3/22

Date: 03 / 22 / 11

To: PM 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 21, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JANELLE KAY
PYXIS REGULATORY CONSULTING, INC.
RITTER CHEMICAL, LLC
4110 136TH STREET, N.W.,
GIG HARBOR, WA 98332-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 16-MAR-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 892170

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 9468 RITTER CHEMICAL, LLC

V

Risk Manager: Registration Division, Risk Management Team 23

Product #: 9468-UL

Product Name: RITTER DICAMBA TECHNICAL

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 11-Mar-2011

OPP Rec'd Date: 16-Mar-2011

Front End Date: 16-Mar-2011

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description: New registration

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

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Tracking

Receipt Content

Study

CSF

View/Edit

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

484206-00
Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

March 11, 2011

OVERNIGHT DELIVERY

Kathryn Montague (PM 23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Ritter Chemical, LLC
Ritter Dicamba Technical (EPA File Symbol 9468-)
Application for New Pesticide Registration
PRIA category R310 (46: New manufacturing use product)

Dear Ms. Montague,

On behalf of Ritter Chemical, LLC, we are submitting an application for registration of Ritter Dicamba Technical. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Three (3) Copies of the Proposed Labeling
4. A CD containing an electronic version of the proposed labeling
5. Certification with Respect to Label Integrity
6. Certification with Respect to Citation of Data (EPA Form 8570-34)
7. Agency Internal Use Copy of the Data Matrix
8. Public File Copy of the Data Matrix
9. Copy of PRIA payment
10. Letter of Authorization
11. Product Specific Data (3 copies of each report):

48420501

Volume 1	830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750, 830.1800	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Description of the Formulation Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Ritter Dicamba Technical. <i>Contains Confidential Business Information.</i>
Volume 2	830.1700, 830.1800	Li, H. Preliminary Analysis and Enforcement Analytical Method of Dicamba TGAI. <i>Contains Confidential Business Information.</i>

48420502

48420503	Volume 3	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.7000, 830.7050, 830.7200, 830.7300	Weller, P. J. Group B Product Chemistry Analysis of Dicamba Technical.
48420504	Volume 4	830.6313, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7100, 830.7220, 830.7300, 830.7370, 830.7520, 830.7550-7570, 830.7840-7860, 830.7950	Tillman, A. M. Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties.

We would like to note that Ritter Chemical, LLC is using the cite-all method of support. As per EPA's interpretations of 40 CFR Parts 152.86(b)(2)(i) and 152.93(b)(2)(i), Ritter Chemical, LLC submitted notices of intent to apply and offers to pay to all companies on the September 30, 2010 Data Submitter's List. This action falls under PRIA category R310 (46: New manufacturing use product) because it is an application for registration for a manufacturing use product identical to a currently registered product. The PRIA fee for this action is \$4,807 and has been paid. The decision timeline is 6 months.

We trust you will find this application complete. However, please feel free to contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL

EPA Registration #	Date Submitted to EPA	Electronic file name
009468-xxxxx	March 11, 2011	009468-xxxxx.20110311.Ritter Dicamba Technical label.v1.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature
Ann M. Tillman
Consultant, Ritter Chemical, LLC

March 11, 2011
Date

There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL, then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.
If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Renae Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423



Ritter Chemical LLC

October 28, 2009

To Whom It May Concern:

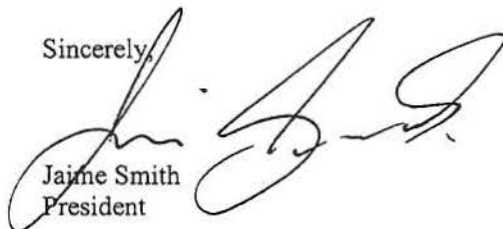
RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agents for Ritter Chemical, LLC (EPA Company Number 9468), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,



Jaime Smith
President

cc: Pyxis Regulatory Consulting, Inc.

Ritter Dicamba Technical
Ann Tillman
to:
Akiva Abramovitch
09/06/2011 01:24 PM
Show Details

Akiva,



Ann

*Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com*

Manufacturing process information may be entitled to confidential treatment

